REMARKS/ARGUMENTS

Claims 1-5, 7-27, and 29-34 are pending in the above-identified application. No claims have been amended in the current response. The Examiner is requested to reconsider the below rejections in view of the remarks below.

Rejections Under 35 U.S.C. §112:

Claims 5 and 15 remain rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is maintained for reasons of record.

As previously stated Applicants will provide a Declaration assuring public availability of the deposited material when allowable subject matter has been indicated. It is understood that the present rejection will be maintained until the assurance is obtained.

Rejections Under 35 U.S.C. § 103

Claims 1-4, 7-14 and 16-34 remain rejected under 35 U.S.C. § 103(a) as being unpatentable over Midthun *et al.* (*J. Virol.* 53:949-954, 1985; designated herein as Midthun '85), Midthun *et al.* (*J. Clin. Microbiol.* 24:822-826, 1986; designated herein as Midthun '86), Hoshino *et al.* (*J. Med. Virol.* 51:319-325, 1997), Clark *et al.* (US. Patent No. 6,113,910; designated herein as Clark *et al.*) and Clark *et al.* (*J. Infect. Dis.* 161:1099-104, 1990; designated herein as Clark *et al.* 1990).

The Examiner has summarized the pending claims being primarily drawn to a multivalent immunogenic composition comprising at least four bovine strain reassortant rotaviruses and a physiologically acceptable carrier, wherein each bovine reassortant rotavirus comprises a single rotavirus VP7 gene that encodes a protein that is immunologically cross-reactive with an antigenically distinct human VP7 serotype and the remaining 10 genes derived from the bovine UK strain, and wherein the composition induces an effective immunogenic

response to each antigenically distinct human rotavirus VP7 serotype without causing a transient low level fever in a statistically significant number of vaccinees when each of the rotavirus reassortant serotype is administered at a dosage of less than $10^{6.0}$ plaque forming units.

The Examiner has again not specifically summarized or addressed claims 22 through 34 as being directed to a method for stimulating the immune system of an infant of less than six months of age to produce an effective immunogenic response to human rotavirus VP7 serotype antigen without significant transient low level fever in a statistically significant number of vaccinees. In fact, the Examiner at page 11 refers to the pending claims as being directed to a vaccine composition and that Applicants continue to discus and argue limitations that are involved in a method of vaccination where a certain dose is given to a subject and there is a certain outcome. Applicants continue with this line of argument in part because the Examiner has not made a showing that the compositions of Clark relating to WC3 can be extrapolated to any composition comprising the bovine rotavirus UK and also because claims 22 through 34 are directed to methods for stimulating the immune system of an infant of less than six months of age to produce an effective immunogenic response to human rotavirus VP7 serotype antigen without significant transient low level fever in a statistically significant number of vaccinees with a composition having the limitations of a certain dose (less than 10^6 pfu) and being given to a subject (infants less than 6 months of age) as discussed further below.

Midthun *et al.* '85 and '86 are alleged by the Examiner to teach four human x bovine reassortant rotaviruses, where the reassortants have one human gene (D (serotype 1), DS-1(serotype 2), P (serotype 3) and ST3 (serotype 4)) from a human rotavirus serotype and where the bovine parent/backbone, which is the UK strain, provides the remaining 10 genes. Midthun *et al.* '85 and Midthun *et al.* '86 are acknowledged by the Examiner not to teach a multivalent immunogenic composition of four reassortant rotaviruses, a physiologically acceptable carrier, nor to teach the induction of an immunogenic response without causing a low level fever, or a dosage.

Clark *et al.*, is alleged by the Examiner to teach combining different human x bovine reassortant rotaviruses into a single composition. Clark *et al.* is also alleged to teach suitable carriers, liquid dose forms, buffers, lyophilized forms, adjuvants, multiple administrations, and methods for stimulating the immune system. Clark *et al.* is further alleged by the Examiner to teach a general dose range between 10^6 and 10^9 and other dosages of $10^{5.5}$, $10^{6.5}$ and $10^{7.5}$.

Clark *et al.* 1990 is alleged by the Examiner to disclose the safety and protective efficacy of a serotype 1 reassortant of bovine rotavirus, which contains a gene segment 9 coding for the surface structural protein VP7 of a human serotype 1 rotavirus, with all other gene segments derived from WC3 rotavirus, which had previously been shown to be safe and immunogenic in infants. The Examiner has cited to portions of Clark *et al.* that allegedly describe the administration to infants 2-11 months of age two doses of vaccine ($10^{7.3}$ plaque-forming units/dose) or of placebo 28 days apart.

Hoshino *et al.* is alleged by the Examiner to teach that the four human serotypes (serotypes 1-4, also disclosed in Midthun *et al.* '85 and '86) are the most epidemiologically important serotypes.

Combining these alleged teaching the Examiner has concluded that it would have been obvious to one of ordinary skill in the art to modify the teachings of Midthun *et al.* '85 and '86 to produce a multivalent composition with two, three, four, five, six, *etc.*, reassortants and that one would have been motivated to do so given the numerous teachings of Clark *et al.*, in particular, the teaching to produce a multivalent composition of reassortants, to include more than one reassortant to elicit a stronger immune response, and to further combine the teachings of Hoshino *et al.* The Examiner has alleged that there would have been a reasonable expectation of success given the fact that it is common and routine to produce multivalent vaccines and given the knowledge that Clark *et al.* successfully vaccinated subjects with reassortant vaccines and also given the knowledge that WC3 strain of Clark *et al.* and the UK strain are of the same serotype (serotype 6). Finally, the Examiner alleges that the prior art references, when

combined, teach or suggest all the claim limitations. Thus, the Examiner has concluded that the claimed invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Applicants must again strongly disagree with the Examiner's rejection. It is not disputed that there is motivation to combine animal rotavirus x human VP7 serotype rotavirus to form prospective vaccine compositions given that it was well known that the VP7 G1 through G4 serotypes were epidemiologically most important. But, the Examiner has alleged that there would be a reasonable expectation of success in producing a multivalent composition with two, three, four, five, six, *etc.* reassortants in producing a multivalent vaccine that would induce an effective immunogenic response to each antigenically distinct human rotavirus VP7 serotype in infants of less than six months of age without causing a transient low level fever in a statistically significant number of vaccinees. In particular, the Examiner alleges that it would be obvious because Clark *et al.* successfully vaccinated subjects with reassortant vaccines and that it was common knowledge that the WC3 strain of Clark *et al.* and the UK strain of the present invention are the same serotype (serotype 6).

On the contrary Clark *et al.* only successfully vaccinated subjects with bovine WC3 x human VP7 G1 serotype rotavirus at an effective concentration of over 10^7 pfu. Applicants previously addressed this issue in the last response, but the Examiner has not provided a response to those arguments.

As presented previously there is no reason to believe that the bovine rotavirus strain WC3 and the bovine rotavirus strain UK would induce the same or similar immune response when administered to an individual, whether the individual were an adult, a child or an infant. The Examiner has alleged that the rotaviruses will induce a similar immune response because the two strains are VP7 serotype 6. The VP7 characterization system is an immunological based system wherein cross reactivity with the VP7 protein of the rotavirus separates the rotavirus into groups. In the reassortant rotavirus either the bovine VP7 or the VP4 protein is replaced with the corresponding human VP7 or VP4 protein. The Examiner has not

provided any evidence that the VP7 or VP4 serologic characterization systems correlate with the ability of a bovine or human rotavirus to grow in an infected host or correlates with the ability of the rotavirus to induce an immune response.

In responding to Applicants prior response, the Examiner has again alleged that it is well known that the WC3 strain of Clark *et al.* and the UK strain are the same serotype citing Gouvea *et al.* (*J. Clin. Microbiol.* 32:1338-1340, 1994) and now citing Midthun and Kapikian (*Clin. Microbiol. Rev.* 9:423-434, 1996). Midthun and Kapikian are cited as stating that "the VP4 specificity by neutralization of WC3 has not been reported, but with regard to genotype, it appears to be similar to UK virus". From these passages the Examiner has concluded that it would be reasonable for one of skill in the art to expect that the UK strain used in Midthun '85 and '86 would behave similarly as the WC3 strain.

Contrary to the allegation of the Examiner, it is well known to the skilled artisan that VP7 and VP4 are considered rotavirus neutralization antigens. As such, antibodies directed to the VP7 and VP4 antigens are developed in individuals infected with the antigens. The antigens have not been correlated with rotavirus infectivity. As such, any relationship between the VP4 antigen of bovine rotavirus strain WC3 and bovine rotavirus strain UK would not lead the skilled artisan to expect that the UK strain used in Midthun '85 and '86 would behave similarly as the WC3 strain.

In addition, the Examiner now cites to a portion of Midthun '85 that states "[t]he single human rotavirus gene substitution reassortants described in this study represent potential vaccine candidates. The neutralization protein of these reassortants is derived from the human rotavirus parent, and these viruses should therefore have the desired immunogenicity. It is also likely that the presence of 10 animal rotavirus genes in these reassortants will render such viruses attenuated for humans. This latter supposition is supported by the fact that bovine rotavirus UK and RRV have been administered to susceptible volunteers with a low level of serum antibodies and did not produce illness. These findings suggest that single human rotavirus gene substitution reassortants may be promising vaccine candidates for use in prevention of human rotavirus

disease". From these passages, the Examiner has alleged that it is reasonable to believe that the UK strain can be substituted for the WC3 in human x bovine reassortants.

Previously, the Examiner has asserted that the UK and WC3 strains of rotavirus will demonstrate the same ability to induce an immunological response because they are both VP7 serotype 6. Applicants must point out that the VP7 gene from both the bovine UK and the bovine WC3 strains are removed in the production of the human x bovine reassortants. As such, the factor associated by the Examiner with providing the necessary link between the two bovine rotaviruses and their ability to produce the same or similar immune response does not exist. Applicants believe the Examiner has not met the burden for stating a *prima facie* case for obviousness.

Applicants must again strongly disagree with the overall allegation of the Examiner that any result obtained with a composition consisting of the r rotavirus strain WC3 can be extrapolated to the bovine rotavirus UK strain. The passages from Midthun '85 only suggest that the UK reassortants may be promising vaccine candidates for use in the prevention of human rotavirus disease. Further, the administration of bovine UK was to adult volunteers that had low levels of preexisting antibodies specific for rotavirus to determine if the composition would cause disease in adults. But, as stated in paragraph 6 of the Kapikian Declaration filed with Applicants' response dated June 29, 2005, "[o]ur experience with human x rhesus rotavirus reassortants and with other non-human animal rotavirus and human x non-human animal rotavirus reassortants has relied on that principle that for exactly the reasons listed by the Examiner above, it is not possible to predict ahead of time whether any particular rotavirus composition will be sufficiently attenuated so as not to cause disease in human vaccinees and still retain sufficient immunogenicity to be effective in inducing an immune response capable of protecting against rotaviral disease". Therefore, it is not reasonable to believe that the rotavirus bovine UK strain can be substituted for the rotavirus WC3 strain in human x bovine reassortants, much less at a concentration of less than 10^6 pfu.

The Examiner next addresses Applicants remarks that Clark *et al.* only successfully vaccinated subjects with bovine WC3 x human VP7 G1 serotype at a concentration of over 10^7 pfu. As above, the Examiner has again summarized Clark *et al.* as teaching severl doses of human x bovine reassortants including a general dose range between 10^6 and 10^9 and other dosages of $10^{5.5}$, $10^{6.5}$ and $10^{7.5}$. In addition, the Examiner cites Clark *et al.* as stating that "30 of 54 infants, or 57%, given any dose of vaccine developed a virus-neutralizing serum antibody response to one or more of rotavirus serotype G1, G3 or bovine". The Examiner further alleges that the "any dose" of Clark *et al.* refers to include the $10^{5.5}$ dose. As such, the Examiner believes that contrary to Applicants' argument, the $10^{5.5}$ dose of Clark *et al.* was effective and provides a reasonable expectation of success for the $10^{5.5}$ does and other doses of human x bovine reassortants, and furthermore, the Examiner believes that because Example 5 used a higher dose ($10^{7.3}$), it does not indicate that the previous dose of $10^{5.5}$ was ineffective. Based on these beliefs, the Examiner again concludes that the combined teachings of Midthun '85, Midthun '86, Clark *et al.* and Clark *et al.* (*J. Infect. Dis.*) teach the claimed invention (an immunogenic composition comprising at least four human x bovine (UK) reassortants) as outlined above.

Applicants must again strongly disagree with the Examiner's conclusions regading Clark *et al.* In particular, the cited phrase "30 of 54 infants, or 57%, given any dose of vaccine developed a virus neutralizing serum antibody response". This phrase provides very little useful information to the skilled artisan. The 30 individuals could have been given any dose, either $10^{5.5}$, $10^{6.5}$, or $10^{7.5}$. In addition, the neutralizing antibody response could have been directed to either VP7 antigen or VP3 antigen from the human rotavirus or could have been directed to one of the components of the rotavirus WC3 strain, such a VP4. There is no information in Clark that would provide the skilled artisan with any guidance that a human x bovine reassortant based on another rotavirus bovine strain would provide an effective composition if used at any concentration. Example 5 is also cited by the Examiner. In this Example, the WI79-3,9 vaccine use used in a clinical trail at a concentration of $10^{7.3}$ pfu. The skilled artisan is provided with additional guidance that when administered at a dosage of $10^{7.3}$ a human x bovine WC3 strain

reassortant consisting of a VP3 and a VP7 antigen from the human rotavirus WI79 and the remaining 9 genes from the bovine rotavirus strain WC3 is well tolerated when given in a three dose regimen in infants and is highly effective at prevention of clinically significant serotype G1 rotavirus infection. This example provides no information relating to Example 4.

As such, although Clark *et al.* may have demonstrated an effective bovine WC3 x human VP3, VP7 composition at a dosage of greater than 10^6 pfu, the characterization of the bovine rotavirus strain WC3 and UK as VP7 serotype 6 provides no information to the skilled artisan relating to the ability of the parental rotavirus or a reassortant rotavirus comprising either WC3 or UK to induce an effective immune response at any dosage, much less at a dosage of less than 10^6 pfu. It is well known to a skilled artisan in the rotavirus art that any prospective vaccine composition must be empirically tested in adults, young children, and then infants to demonstrate with any reasonable expectation the ability of the composition to induce an effective immune response, much less the minimum dosage of the prospective composition necessary for inducing an effective immune response. Applicants again direct the Examiner to paragraph 6, lines 24-31, wherein Dr. Kapikian states "[i]n the present case, the prior bovine rotavirus and human x bovine rotavirus reassortants were found to be highly attenuated in humans, typically requiring greater than 10^7 to 10^8, or more, plaque forming units of virus to obtain an effective immunogenic response in vaccinees. By extrapolation from the prior art it might be anticipated that the human x bovine UK reassortant compositions of the present invention would not be capable of inducing an acceptable immune response to each antigenically distinct human rotavirus VP7 serotype included in the composition in a meaningful number of vaccinees at a concentration of less than 10^6 pfu."

The Examiner has reviewed the Clark *et al.* reference (Vaccine 8:327-332, 1990) and concluded that although it teaches infants of 12 months of age, and not less than 6 months of age, the reference has no bearing on the teachings of the Clark patent. In addition, the Examiner alleges that even assuming that the Clark *et al.* Vaccine reference does establish that the Clark patent ('910 patent) did not vaccinate infants less than 6 months of age, it does not preclude the fact that it would be obvious to one of ordinary skill in the art to vary the dose of vaccine

depending on the subject. As an example, the Examiner states that it would be obvious to administer lower doses of vaccine to infants given the fact that infants are smaller than adults (vaccine does are determined by body weight). Further, the Examiner believes that it would be obvious to administer lower doses of vaccine to decrease the number of side effects, if there are any. In addition, the Examiner relies on the Clark *et al.* patent (the '910 patent) as teaching several dosages of human rotavirus x bovine rotavirus WC3 strain reassortants, including dosages of $10^{5.5}$, $10^{6.5}$ and $10^{7.5}$, as well as teaching the administration of human rotavirus x bovine rotavirus WC3 strain reassortants to adults and children. Further, the Examiner repeats that allegation that it would be reasonable to expect the WC3 and UK strains to produce similar results because they are similar genotypically and that it would be routine experimentation to determine other doses to administer to adults and infants of any age given the teaching of Clark *et al.* and Midthun *et al.*

As above, the Examiner has not made a case for *prima facie* obviousness. Further, the Examiner alleges that it would be obvious to administer lower dosages of vaccine to infants based on results in adults. Applicants again direct the Examiner to the Kapikian Declaration, wherein Dr. Kapikian states "[o]ur experience with human x rhesus rotavirus reassortants and with other non-human animal rotavirus and human x non-human animal rotavirus reassortants has relied on that principle that for exactly the reasons listed by the Examiner above, it is not possible to predict ahead of time whether any particular rotavirus composition will be sufficiently attenuated so as not to cause disease in human vaccinees and still retain sufficient immunogenicity to be effective in inducing an immune response capable of protecting against rotaviral disease". Further, it is well known to the skilled artisan that infants less than 6 months of age can have maternal antibodies specific for rotavirus dramatically affecting the ability of the administered rotavirus composition to induce an effective immunogenic response. Also, it is well know to a skilled artisan that adults, children and some young typically have been previously infected by rotavirus and as such immunization with a rotavirus composition typically induces a secondary antibody response. Therefore, the skilled artisan does not have a reasonable expectation that any result obtained with an human rotavirus x

bovine rotavirus WC3 reassortant would be relevant to a human rotavirus x bovine UK strain reassortant at any concentration, mush less at a concentration of less than 10^6 pfu.

Applicants further disagree with the Examiner that the present invention is merely the optimization of a dosage. In *In re Peterson* previously cited by the Examiner, the Court held that a *prima facie* case of obviousness can be overcome by providing a showing that the critical characteristic resulted in an unexpected result. In the present case, methods for testing rotavirus vaccine compositions are generally known in the art. Typically, a prospective rotavirus vaccine composition is tested first in adults and young children to determine safety prior to testing for efficacy in infants. The prospective rotavirus vaccine composition is also typically tested at a number of different dosages. In the present case, Clark *et al.* merely demonstrate that the bovine WC3 reassortant rotavirus composition was effective in infants of 2 to 11 months at a dosage of $10^{7.3}$ pfu. As above, no reasonable prediction can be made as to efficacy of a rotavirus vaccine composition in infants 6 months of age and younger even after safety and efficacy of the composition in adults or in young children has been demonstrated. (See paragraph 6 of the Kapikian Declaration). In particular, the amount of attenuation and immunogenicity for a particular prospective vaccine composition can not be predicted. The lack of predictability, as set forth above, partially lies in the fact that infants of 6 months of age and younger have maternal anti rotavirus antibodies that can affect the ability of the live rotavirus composition to grow in the infant and to induce an effective immune response.

In addition, Clark *et al.* do not disclose a bovine reassortant composition wherein each reassortant rotavirus comprises only a VP7 antigen immunologically cross-reactive with a human VP7 serotype and the remaining genes from a bovine rotavirus at a dosage of less than 10^6 pfu that is effective inducing an immune response in an infant of less than 6 months of age. Example 4 cited by the Examiner discloses a reassortant vaccine composition that consists of a human bovine reassortant wherein the VP3 and VP7 genes from a G1 serotype human rotavirus and the remaining genes are from the bovine rotavirus strain WC3. See, column 4, lines 42-53, Table 1 at column 5, subscript *a*, and column 10, lines 49-57. Further, as noted previously and above, Clark *et al.* disclose that the composition was administered at various concentrations,

recited as $10^{5.5}$, $10^{6.5}$, and $10^{7.5}$ pfu to children of various ages. In Example 4 at column 12, lines 58 - 64, Clark *et al.* state "30 of 54 infants, or 57%, given any dose of vaccine developed a virus-neutralizing serum antibody response to one or more of rotavirus serotypes G1, G3 or bovine." As such, Clark *et al.* disclose that 57% of all infants administered the vaccine had neutralizing antibody to any of WC3, WI79, or SA11 (a human rotavirus stain of VP7 serotype 3). No data is provided that indicates whether any of the vaccinees that received the dosage of $10^{5.5}$ had developed neutralizing antibody, nor does the example provide any information relating to the age of the infants that received this dosage of vaccine. As such, Clark provides no disclosure that provides any guidance to a skilled artisan that supports the use of a single gene substitution, *e.g.*, VP7, in a bovine UK rotavirus background. Further, the statement cited by the Examiner merely says that 57% of the vaccinees that received a dose of the composition at some concentration developed a virus-neutralizing serum antibody response to a rotavirus antigen. The tested antigens were VP7, VP3 and WC3 bovine. The skilled artisan can draw no reasonable conclusion about the effectiveness of the administration of specifically the $10^{5.5}$ dosage amount. Review of the remainder of the reference provides the skilled artisan with the teachings that the general dosage for a vaccine composition is from 10^6 to 10^9 and the remainder of the studies used a dosage of greater than 10^7 pfu.

The Examiner has noted that the claimed invention is a vaccine composition comprising at least four bovine strain reassortant rotaviruses and a physiologically acceptable carrier, wherein each bovine reassortant rotavirus comprises a single rotavirus VP7 gene that encodes a protein that is immunologically cross-reactive with an antigenically distinct human VP7 serotype and the remaining 10 genes derived from the bovine UK strain. The Examiner has asserted that the composition has been disclosed in the prior art as outlined above. Further, the Examiner appears to admonish Applicants for continuing to discuss and argue limitation that are alleged to be involved in a method of vaccination where a certain dose (less than 10^6 pfu) is given to a subject (infants less than 6 months of age) and there is a certain outcome (low level fever). The Examiner alleges that these limitations do not further describe the composition or components of the composition, but only describe the subject to be vaccinated, the dose to be

administered, and a characteristic of the composition after it has been administered an a method for vaccination.

Applicants first note that as above, claims 22 through 34 are directed to a method for stimulating the immune system of an infant of less than six months of age to produce an effective immunogenic response to human rotavirus VP7 serotype antigen without causing transient low level fever in a statistically significant number of vaccinees, which comprises administering a multivalent immunogenic composition comprising at least four bovine UK strain reassortant rotaviruses, wherein each bovine reassortant rotavirus comprises a single VP7 gene which encodes a protein immunologically cross-reactive with an antigenically distinct human VP7 serotype and the remaining 10 genes derived from the bovine UK rotavirus strain each administered at a dosage of less than $10^{6.0}$ plaque forming units and a physiologically acceptable carrier. As previously submitted, Applicants do not believe that the Examiner has specifically addressed the subject matter of claims 22 through 34. Applicants respectfully request that the Examiner consider claims 22 through 34 separately from the compositions claims.

In addition, as the Examiner has not demonstrated that it would have been reasonable for the skilled artisan to extrapolated any conclusions relating to human rotavirus x bovine rotavirus WC3 strain reassortants to human x bovine UK strain reassortants, the compositions of pending claims 1 through 21 have not been disclosed in the art. As such, the limitations relating to rotavirus strain, dosage, and age of the vaccinee in which the composition would be effective are proper to define the patentable compositions as well as methods. As above, there is no reasonable expectation that a bovine rotavirus UK strain reassortant with an antigenically distinct human VP7 serotype and the remaining 10 genes from the UK strain would provide a safe, effective response in infants of less than six months of age based on the results of Clark *et al.* using a bovine WC3 strain reassortant with a human VP7 and VP3 genes and the remaining 9 genes from the bovine WC3 strain. As such, Applicants respectfully request the Examiner to reconsider and withdraw the rejection of claims 1-4, 7-14 and 16-34 under 35 U.S.C. § 103(a) as being unpatentable over Midthun *et al.* (*J. Virol.* 53:949-954, 1985; designated herein as Midthun '85), Midthun *et al.* (*J. Clin. Microbiol.* 24:822-826, 1986;

designated herein as Midthun '86), Hoshino *et al.* (*J. Med. Virol.* 51:319-325, 1997), Clark *et al.* (US. Patent No. 6,113,910; designated herein as Clark *et al.*) and Clark *et al.* (*J. Infect. Dis.* 161:1099-104, 1990).

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is respectfully requested. If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 206-467-9600.

Respectfully submitted,

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